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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,477	04/15/2004	Fabio Soldati	01-1490	8137

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EXAMINER

MAEWALL, SNIGDEHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,477

Applicant(s)

SOLDATI ET AL.

Examiner

Snigdha Maewall

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments and RCE filed on 11/18/08 is acknowledged.

Claims 3-4 remain cancelled.

Claims **1-2 and 5-20** are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-2 and 5-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "suitable" carrier". The term suitable makes the claim indefinite since it is not clear which ingredients are suitable. The term suitable in claim 1 is a relative term which renders the claim indefinite. The term suitable is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. claim 1 as recites the limitation consisting of one or more vitamins, however, it the metes and bounds of vitamins are not defined in the claim

which makes the claim indefinite. It is unclear which vitamins are included and which are not.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (WO 95/35098) in view of Engel (USP 6,368,621 B1) and further in view of deVries et al. (US Patent No. 6,495,177 B1)

Paradissis et al. teach multi-vitamin and mineral supplements for administration to lactating, non-lactating, and menopausal women, which comprise specific regimens of critical nutritional agents. The supplements are specifically tailored to meet nutritional requirements and maintain a woman's health during each stage of life (abstract). The reference teaches calcium, vitamin D, beta carotene, vitamin D, A, B12, B6, B3, B1, B2, iron and zinc (see page 4, the entire page). The reference teaches molybdenum and chromium in the composition (see page 6, lines 10-20). The reference also discloses magnesium and discloses that other ingredients may be added to the

formulation (see page 10, lines 30-35 and page 11, lines 8-10. Various ingredients that may be added in various release format are thiamine, niacinamide, pyridoxine, ascorbic acid, folic acid, ribiflavin, biotin, pantothenic acid, copper, potassium, iodine as disclosed on page 11, lines 1-5. Various amounts of various ingredients have been disclosed in examples and claims.

Paradissis et al. do not teach DHA in the formulation, however, Engel discloses iron complexes and DHA in formulation.

Engel discloses an invention related to a preparation which contains at least one physiologically effective iron complex and at least one polyunsaturated fatty acid in free or chemically bonded form, in particular for use as a medication and/or food supplement. The preparation according to the invention may be preferably used for manufacturing a medication and/or food supplement for treating or the prevention of deficiency symptoms as they may occur during pregnancy and breastfeeding. (abstract). Furthermore antioxidizing agents and folic acid may be contained in the preparation according to the invention (abstract). The reference teaches DHA see examples in column 7 and 8.

Engel further discloses that Iron has a particular importance with regard to minerals and trace elements. The iron requirement of mother and child is an important factor of prenatal and postnatal health on account of the build-up of special fetal hemoglobin, whose conversion after birth serves in filling the iron store in kidney and liver. Engel teaches importance of iron complex uptake.

deVries teaches an orally administrable nutritional supplement which is highly palatable, such as a chewable prenatal vitamin/mineral supplement. The supplement is preferably made in the form of a tablet that, upon chewing, dissolves rapidly in the mouth. The tablet is particularly suitable for administration of vitamins and minerals to women during pregnancy. The invention also includes methods of making and using such supplements (abstract). The invention comprises vitamins, carotene, iron, flavorants etc. Calcium is excluded from the solid dosage form or if present is in less than therapeutic amount DeVries further teaches that preferred absence of calcium from the tablet ensures minimal interference of iron absorption by minerals present in the tablet. (see column 7, lines 5-53 and column 11 ,lines 28-35).

It would have been obvious to add iron complexes and DHA in the composition of Paradissis et al. because iron complexes and DHA are taught to be helpful nutritional source by Engel et al. Additionally, Since Engel teaches importance of iron, one would have been motivated not to add calcium in the combined teachings of Paradissis and Engel et al. as deVries teaches that absence of calcium from the tablet ensures minimal interference of iron absorption by minerals.

With respect to the weight ratios of various components and amounts, it is the examiners position that optimization of such parameters are within the purview of a skilled artisan by doing experimental manipulation absent evidence to contrary. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable range by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

6. Applicant's arguments with respect to claims 1-2 and 5-20 have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612